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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/347,064	07/02/1999	JURGEN ECK	09282-5(B352	3271

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AKIN GUMP STRAUSS HAUER & FELD L.L.P.
ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103

EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/347,064	ECK ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/30/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15,16,18-27,29,33-37,48 and 50-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15,16,18-27,29,33-37, 48 and 50-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-13, 15, 16, 18-27, 29, 33-37, 48, and newly added Claims 50-52, are being acted upon. **NOTE**: Claim 49 was previously cancelled. Accordingly, new Claims 49-51 have been renumbered as Claims 50-52 under Rule 1.126.

2. Applicant's amendment and remarks, filed 11/30/05, are acknowledged. In view of Applicant's amendment, the previous rejections under 35 U.S.C. 112, first paragraph, for lack of enablement have been withdrawn. Additionally, the previous rejections for lack of written description relating to nucleic acid fragments and nucleic acids comprising substitutions, insertions, additions or exchanges, as well as the rejection related to degenerate cells of the immune system have been withdrawn. Additionally, the previous objection to the specification has also been withdrawn.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-13, 15, 16, 18-27, 29, 33-37, 48, and newly added Claims 49-51 stand/are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

As set forth previously, "there is insufficient written description to show that Applicant was in possession of the effector, targeting, and modulator modules of the instant claims.

Regarding the effector module of the instant claims, the specification at pages 11-12 discloses that the effector module encompasses not only modules that are toxic, but also modules that "modify the vital processes of the target cells", e.g., impaired "metabolic processes, particularly processes of the energy metabolism, molecular-genetic processes, particularly translation, transcription and replication and specific cellular reaction sequences such as, e.g., the induction of apoptotic processes". Clearly, this term is intended to encompass a huge genus of effector modules, none of which, other than a single toxin (MLA), have been described. Thus, a

representative number of the claimed nucleic acids have not been described.

Regarding the targeting module of the instant claims, the specification at page 13 discloses that the targeting module is "capable of allowing access of the fusion protein according to the invention to the cell's core via a specific affinity to a cell surface protein". Just a single example, of a cell surface protein meeting the required internalization limitation is disclosed (MHC). And indeed, only MHC Class II molecules actually meets the limitation allowing access to the cell's core (the more prevalent MHC Class I molecules would not be expected to be internalized). The claim at least implies, incorrectly, that any cell surface protein would allow access to a cell's core. Regardless, the single, only partially correct, example of a targeting module (MHC-binding peptides) does not comprise a representative number of the claimed nucleic acids.

Regarding the modulator module of the instant claims, the specification at page 17 discloses that the modulator module is capable of intracellularly modulating the cytotoxic effect of an effector module and include modules that assist in membrane translocation or those that participate in intracellular transport mechanisms. Just a single example, rMLB is disclosed. Again it is clear that this term is intended to encompass a huge genus of molecules, just one of which has been described. Thus, again, a representative number of the claimed nucleic acids have not been described.

Applicant's arguments, filed 11/30/05 have been fully considered but they are not persuasive. Applicant has not specifically addressed these grounds for rejection.

For further clarification, each of the claims recites a nucleic acid molecule encoding at least one "module" for which an inadequate written description is provided. For example, the targeting modules of Claims 1 and 34 are inadequately described, as are the targeting and modulator modules of Claim 4.

5. The following are new grounds for rejection.

6. Claims 49-51 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) the MHC II targeting module of Claim 49,
B) the bFGF targeting module of Claim 50,

Applicant indicates support of A) at page 24 of the specification.

The cite at page 24 discloses "allergenic peptides which normally present MHCII as targeting modules" and not MHC II targeting modules.

Applicant indicates support of B) at the paragraph bridging pages 34 and 35 of the specification

The cite discloses a bFGF targeting module and not a bFGF processing module.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically, the claim depends from Claim 1 which recites a nucleic acid encoding a fusion protein comprising (at a minimum) an effector, targeting, and processing module. The constructs of Claim 51, however, consist of just an effector and targeting module, or an effector, targeting, and modulating module. Accordingly, the claim does not comprise all of the limitations of the claim on which it depends.

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 22, 25, 27, and 29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims encompass a transgenic human and a method of use of a transgenic human.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from

7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

13. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/7/06

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600